Steven J. Lee
KENYON & KENYON LLP
One Broadway
New York, New York 10004-1050
Phone (212) 425-7200
Fax (212) 425-5288

Counsel for Defendants

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, and NOVARTIS AG, Plaintiff, v. SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 12-04393 (SDW)(MCA)

ANSWER

Defendants Sun Pharma Global FZE ("Sun FZE") and Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") (collectively, "Sun"), by and through their undersigned attorneys, answer plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation, and Novartis AG's (collectively, "Plaintiffs" or "Novartis") complaint dated July 13, 2012 ("Complaint") as follows:

Nature of the Action

1. Admitted that Plaintiffs purport to bring this action under the patent laws of the United States, Title 35, United States Code, for alleged infringement of the United States Patent No. 7,932,241 ("'241 patent"), and that Sun FZE filed ANDA Nos. 204051 and 204138. Otherwise denied.

The Parties

2. Sun is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 2 and, therefore, denies them.

3. Sun is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 3 and, therefore, denies them.

4. Sun is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 4 and, therefore, denies them.

5. Sun Pharmaceutical Industries Inc. ("Sun Inc.") is no longer a defendant in this action, and thus this paragraph is denied as moot.

6. Sun Inc. is no longer a defendant in this action, and thus this paragraph is denied as moot.

7. Sun admits the allegations of this paragraph with the clarification that Sun FZE is an entity organized and existing under the laws of Sharjah, United Arab Emirates.

8. Sun admits that Sun FZE has submitted to the FDA Abbreviated New Drug Applications seeking approval to market drug products. Otherwise denied.

9. Caraco Pharmaceutical Laboratories Ltd. ("Caraco") is no longer a defendant in this action, and thus this paragraph is denied as moot.

10. Caraco is no longer a defendant in this action, and thus this paragraph is denied as moot.

11. Sun admits that Sun FZE is a subsidiary of Sun Pharma Global Inc., which is a subsidiary of Sun Ltd., and that Sun Inc. is a subsidiary of Sun Ltd. Otherwise denied.

12. Sun admits that Sun Ltd. is an entity organized and existing under the laws of India, with a principal place of business at Acme Plaza, Andheri-Kurla Road, Andheri (E), Mumbai, 400 059, India. Otherwise denied.

13. Sun admits that Sun Ltd. is in the business of developing and manufacturing pharmaceutical drug products and has sold and distributed to an affiliate located in the State of Michigan drug products for resale in the United States. Otherwise denied.

14. Denied.

15. Sun admits that Sun FZE submitted to the FDA Abbreviated New Drug Application ("ANDA") Nos. 204051 and 204138. Sun further admits that Sun Ltd. developed the products that are the subjects of ANDA Nos. 204051 and 204138. Otherwise denied.

16. Denied, except as admitted in Paragraph 15.

17. Denied.

18. This paragraph does not contain averments of fact which can be either admitted or denied.

Jurisdiction and Venue

19. Admitted.

20. Sun has consented to jurisdiction and venue in this district for this action. Otherwise denied.

21. Sun Inc. is no longer a defendant in this action, and thus this paragraph is denied as moot.

22. Sun Inc. is no longer a defendant in this action, and thus this paragraph is denied as moot.

23. Sun incorporates its response to Paragraph 21.

24. Sun has consented to jurisdiction and venue in this district for this action. Otherwise denied.

25. Sun incorporates its response to Paragraph 24.

26. Caraco is no longer a defendant in this action, and thus this paragraph is denied as moot.

27. Caraco is no longer a defendant in this action, and thus this paragraph is denied as moot.

28. Sun incorporates its response to Paragraph 24.

29. Sun incorporates its response to Paragraph 24.

30. Sun incorporates its response to Paragraph 24.

31. Sun incorporates its response to Paragraph 24.

32. Sun incorporates its response to Paragraph 24.

Facts As to All Counts

33. Sun admits that the ’241 patent, on its face, is entitled “Pharmaceutical Products Comprising Bisphosphonates,” states that it issued April 26, 2011, and states that the assignee is Novartis AG. Otherwise denied.

34. Sun admits that the ’241 patent is listed for Zometa in the Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) published by the

FDA. Sun is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 34 and, therefore, denies them.

35. Sun admits that the ’241 patent is listed for Reclast in the Orange Book. Sun is without knowledge or information sufficient to form a belief as to the truth of the remaining averments in Paragraph 35 and, therefore, denies them.

36. Sun admits that by letter dated June 1, 2012 (“Sun FZE’s First Notice Letter”), Sun FZE notified Novartis pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) that Sun FZE’s ANDA No. 204051 contains a paragraph IV certification for the ’241 patent and seeks approval to market Sun FZE’s drug product before the expiration of the ’241 patent. Otherwise denied.

37. Sun admits that ANDA No. 204051 includes information required by the FDA under 21 U.S.C. § 355(j). Otherwise denied.

38. Admitted.

39. Sun admits that by letter dated July 5, 2012 (“Sun FZE’s Second Notice Letter”), Sun FZE notified Novartis pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) that Sun FZE’s ANDA No. 204138 contains a paragraph IV certification for the ’241 patent and seeks approval to market Sun FZE’s drug product before the expiration of the ’241 patent. Otherwise denied.

40. Sun admits that ANDA No. 204138 includes information required by the FDA under 21 U.S.C. § 355(j). Otherwise denied.

41. Admitted.

42. Admitted that Sun sent a First Notice Letter dated June 1, 2012 and a Second Notice Letter dated July 5, 2012, and that Novartis filed its complaint dated July 13, 2012. Otherwise denied.

Count I

43. Sun repeats and realleges its responses to each of the foregoing paragraphs as if fully set forth herein.

44. Sun admits that the filing of its ANDAs with Paragraph IV certification is a technical act of infringement of the '241 patent under 35 U.S.C. § 271(e)(2). Otherwise denied.

45. Denied.

46. Sun admits that Sun FZE knew of the '241 patent when it filed ANDA Nos. 204051 and 204138, and was aware that filing of those ANDAs with a paragraph IV certification to the '241 patent, constituted a technical act of infringement under 35 U.S.C. 271(e)(2). Otherwise denied.

47. Denied.

Affirmative Defenses

48. For its further and separate defenses to the allegations of the Complaint, and without assuming any burden of proof it would otherwise not bear under applicable law, Sun pleads as follows:

First Affirmative Defense

49. Novartis fails to state a claim on which relief can be granted.

Second Affirmative Defense

50. Sun has not infringed, does not infringe, and will not by the manufacture, use, sale, offer for sale, or importation of the products described in Sun FZE's ANDA

Nos. 204051 and 204138 infringe, directly or indirectly, any valid and enforceable claim of the ’241 patent.

Third Affirmative Defense

51. The claims of the ’241 patent are invalid for failure to comply with one or more of the provisions of Part II of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

Prayer for Relief

WHEREFORE, Sun respectfully requests that the Court:

A. dismiss with prejudice the entirety of Novartis’s Complaint;

B. deny all remedies and relief sought by Novartis;

C. enter judgment in favor of Sun and against Novartis on all claims;

D. adjudge and declare that the claims of the ’241 patent are invalid;

E. adjudge and declare that Sun does not directly and/or indirectly infringe, and has not directly and/or indirectly infringed, any valid and enforceable claims of the ’241 patent;

F. adjudge and declare that Sun will not directly and/or indirectly infringe any valid and enforceable claim of the ’241 patent by the commercial manufacture, use, sale or offer for sale in the United States, or importation into the United States, of the products described in Sun FZE’s ANDA Nos. 204051 and 204138;

G. declare this to be an exceptional case under 35 U.S.C. § 285 and award Sun its attorneys’ fees, costs, and expenses in this action;

H. award Sun its costs and expenses; and

I. award Sun such other and further relief as the Court deems just and appropriate.

Respectfully submitted,

Dated: October 19, 2012

/s/ Steven J. Lee
KENYON & KENYON LLP
One Broadway
New York, New York 10004-1050
Phone (212) 425-7200
Fax (212) 425-5288

Of Counsel:
Robert V. Cerwinski
Thomas F. Lavery, IV
KENYON & KENYON LLP
One Broadway
New York, New York 10004-1050
Phone (212) 425-7200
Fax (212) 425-5288

Counsel for Defendants

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd., by their undersigned counsel, certify that the patent asserted by plaintiffs in this action is also the subject of *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 12-cv-03967-SDW-MCA (D.N.J.), filed on June 27, 2012 in the United States District Court for the District of New Jersey.

Dated: October 19, 2012

Respectfully submitted,
/s/ Steven J. Lee

Steven J. Lee
KENYON & KENYON LLP
One Broadway
New York, New York 10004-1050
Phone (212) 425-7200
Fax (212) 425-5288

Of Counsel:
Robert V. Cerwinski
Thomas F. Lavery, IV
KENYON & KENYON LLP
One Broadway
New York, New York 10004-1050
Phone (212) 425-7200
Fax (212) 425-5288

Counsel for Defendants
Sun Pharma Global FZE
Sun Pharmaceutical Industries Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on October 19, 2012 copies of the foregoing *Answer*, *Certification Pursuant to Local Civil Rule 11.2*, and *Disclosure Statement Pursuant to Fed. R. Civ. P. 7.1* were served on the following counsel of record by ECF and email:

William J. O'Shaughnessy, Esq.
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
woshaughnessy@mccarter.com

Robert J. Gunther, Jr., Esq.
Jane M. Love, Ph.D., Esq.
Sadaf R. Abdullah, Esq.
WILMER CUTLER PICKERING
HALE AND DORR LLP
399 Park Avenue
New York, NY 10022
robert.gunther@wilmerhale.com
jane.love@wilmerhale.com
sadaf.abdullah@wilmerhale.com

Lisa J. Pirozzolo, Esq.
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
lisa.pirozzolo@wilmerhale.com

/s/ Thomas F. Lavery, IV
Thomas F. Lavery, IV
KENYON & KENYON LLP